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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,186	10/09/2001	David Reginald Adams	040283-0192	7541

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09/06/2002

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 09/06/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,186	ADAMS ET AL.	
	Examiner	Art Unit	
	Venkataraman Balasubramanian	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 21-25, 28, 30, 32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 and 28-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 29, 32 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5 & 7</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group VIII, claims 1-18, 32 and 34 drawn to compound of formula I where X^1 , X^2 , X^3 and X^4 in Paper No. 10 is acknowledged. Claims 1-18, 32, 34 will be examined to the extent they embrace the elected subject matter. Claims 21-25 and 28-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter.

The traversal is on the ground(s) that there is common utility and substantial structural identity. This is not found persuasive for following reasons.

1. First of all both the above requirements are to be met with.

As stated in the previous office action, both these requirements are lacking as instant compound has more than one utility as claimed in claims 21 through 30. A prior art, which reads on instant elected utility obesity, would not be applicable treating stroke or schizophrenia and all other disease/disorders embraced instant claims unless applicants admit for the record that method of treating all these disease/ disorders with the instant compound are equivalent.

Applicants rely on mode of action of the compound, namely its binding to HT2 receptor as a utility but if that is a utility then claims 21-30 are reciting additional utility for the instant compounds which by itself negate the common utility asserted by the applicants.

2. As stated in the previous office action the instant compound embraced by varying core groups constitute structurally dissimilar compounds. They are independent and distinct as the process of making and using them are different. They need

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not be used in combination. Furthermore, prior art, which reads on the instant elected or renders it an obvious variant, may not be applicable to non-elected heterofused ring systems.

Hence the instant claims fail to meet both the requirement stated above.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18,32 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim.

1. Recitation of the term "prodrug" in claim 1 is deemed as indefinite. Prodrugs in general and as noted in specification, page 7, are compounds, which undergo in vivo hydrolysis to parent active drug. These are in general esters, amides, carbamoyl etc. In that sense recitation of prodrug is acceptable. However, the various variable groups permitted in the compound of formula I also include such groups which are also likely to undergo the said transformation to the parent compound. It is not clear in that sense what is the prodrug that is being recited in the claim. Is it structurally different from the groups such alkoxycarbonyl amides etc recited for variable groups? If so what is it and what way one would regard the

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"prodrug" as different from above said groups if present in a compound is not clear.

2. Claim 29, which appears to be the claim elected by the applicants as a specific method of treating specific disease, is indefinite as it depends on the non-elected claim 21 and lacks as such all the limitation. An appropriate correction is needed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 12-14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Jonas et al. US 3,853,878.

Jonas et al. teaches several heaxahydropyrazino[1,2-a]indole compounds, which include those claimed herein. See compound of formula II on col. 1, line 50 and note the definition of R. See col. 2 for compounds made, See example 2. Hence it is held that in order to make compounds shown in example 2, Jonas et al. had inherently made the intermediates, which are claimed herein. Note In re Petering et al 133 USPQ 275; In Re Schaumann, 195 USPQ 5.

Claims 1-8, 12, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Duggan et al. US 5,854,245.

Duggan et al. teaches several fibronectin receptor antagonists which include intermediate compounds, which are also claimed in the instant claims.

See scheme 9 on col. 43-44 and compounds made on col. 47-48.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 12-14, 16 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mokrosz et al., Med. Chem. Res. 3: 240-248,1993.

Mokrosz et al. teaches rigid arylpiperazines as CNS agents, which include a compound with ethyl group on the piperazine ring. See compound 7 on page 241, and process of making on page 247.

While said compound doesn't anticipate the scope of instant claims in view of the proviso in claim 1, they are very closely related, having a methyl group on the phenyl ring vs. unsubstituted phenyl ring compound of the reference. However, compounds

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that differ only in having H vs Me are not deemed patentably distinct absent evidence of superior or unexpected properties. See for compounds that differ only as H vs Me in the phenyl ring, In re Wood 199 USPQ 137; In re Lohr 137 USPQ 548. Thus it would have been obvious to one skilled in the art at the time of the invention was made to expect instant compounds to possess the utility taught by the applied art in view of the close structural similarity outlined above.

References cited in the Information Disclosure Statements (paper # 5 & 7) are made of record.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

V. Balasubramanian
Venkataraman Balasubramanian

9/5/2002